HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER CIN-WL -5566 -01

February 22, 2001

Edwin V. Ringer
Co-owner
Hartville Elevator Company, Inc.
111 North Prospect Street
Hartville, Ohio 44632

Dear Mr. Ringer:

An inspection of your feed mill was conducted by a Food and Drug Administration (FDA) investigator on November 15,2000. This inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found your procedures to prevent cross contamination are inadequate in that:

- Your firm has no written procedures to prevent mixing feeds which contain prohibited protein with feeds intended for use in ruminant animals.

- You do not document the steps you do take to prevent cross contamination.

Further the investigation found that you do not track the use of prohibited materials from processing through distribution.

- You do not always identify the purchaser of feeds containing animal proteins by name and address. Producers using these feeds are responsible for their proper use and are not exempt from inspection and being identified by their source of the feeds containing the prohibited proteins.

- Records required by the regulations either do not exist or are not readily available for FDA inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. At the conclusion of the Inspection the investigators provided you a written list of objectionable conditions to which you

indicated you would consider. However, FDA has heard no response as to changes you have made to come into compliance with these regulations. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

In addition to the deficiencies noted above, the adequacy of a flush of your mixer using 150 to180 pounds of ground corncobs seems unlikely. You should establish that the flush method you use cleans out the remainder of preceding batches that contained mammalian proteins and may be adhering to the surface of the mixer in response to some of the feeds having contained molasses. If you have the adequacy already documented please provide FDA with a copy of the record as part of your response. The flush operation should also assure that no equipment used in common with feeds containing prohibited protein can contaminate feeds intended for use in ruminants.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Leonard Jay Farr, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (513) 679-2700.

Sincerely yours,

Henry L. Fielden

Henry L. Fielden
District Director

Enclosure: Small Entity Compliance Guide